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Asfora

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(54) **SUBDURAL EVACUATING PORT SYSTEM**

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(51) **Int. Cl.**
B65D 69/00 (2006.01)

(52) **U.S. Cl.** **206/570**; 604/541; 604/27

(58) **Field of Classification Search** 206/363–366, 206/570–572, 438, 440, 803; 604/541, 27, 604/93.01
See application file for complete search history.

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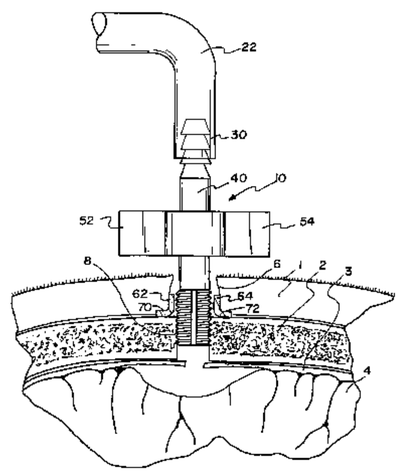
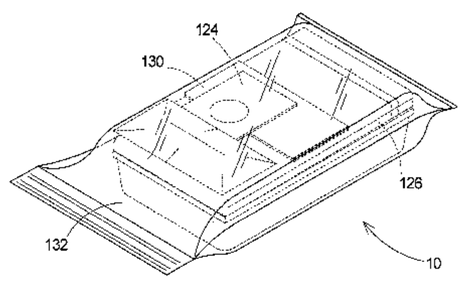
(57) **ABSTRACT**

A kit for evacuating a collection of fluid from the subdural space of a patient is disclosed, and includes a subdural evacuating port device having a proximal end and a distal end. The subdural evacuating port device has a tubular portion with a lumen extending between the proximal and distal ends. An exterior surface of the proximal end of the tubular portion has self-tapping threads formed thereon for cutting threads into a skull. Retaining elements are located on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion. A pair of wings extend outwardly from the tubular portion in opposite directions. The kit also includes elements for performing placement of the subdural evacuating port device in the patient.

25 Claims, 8 Drawing Sheets





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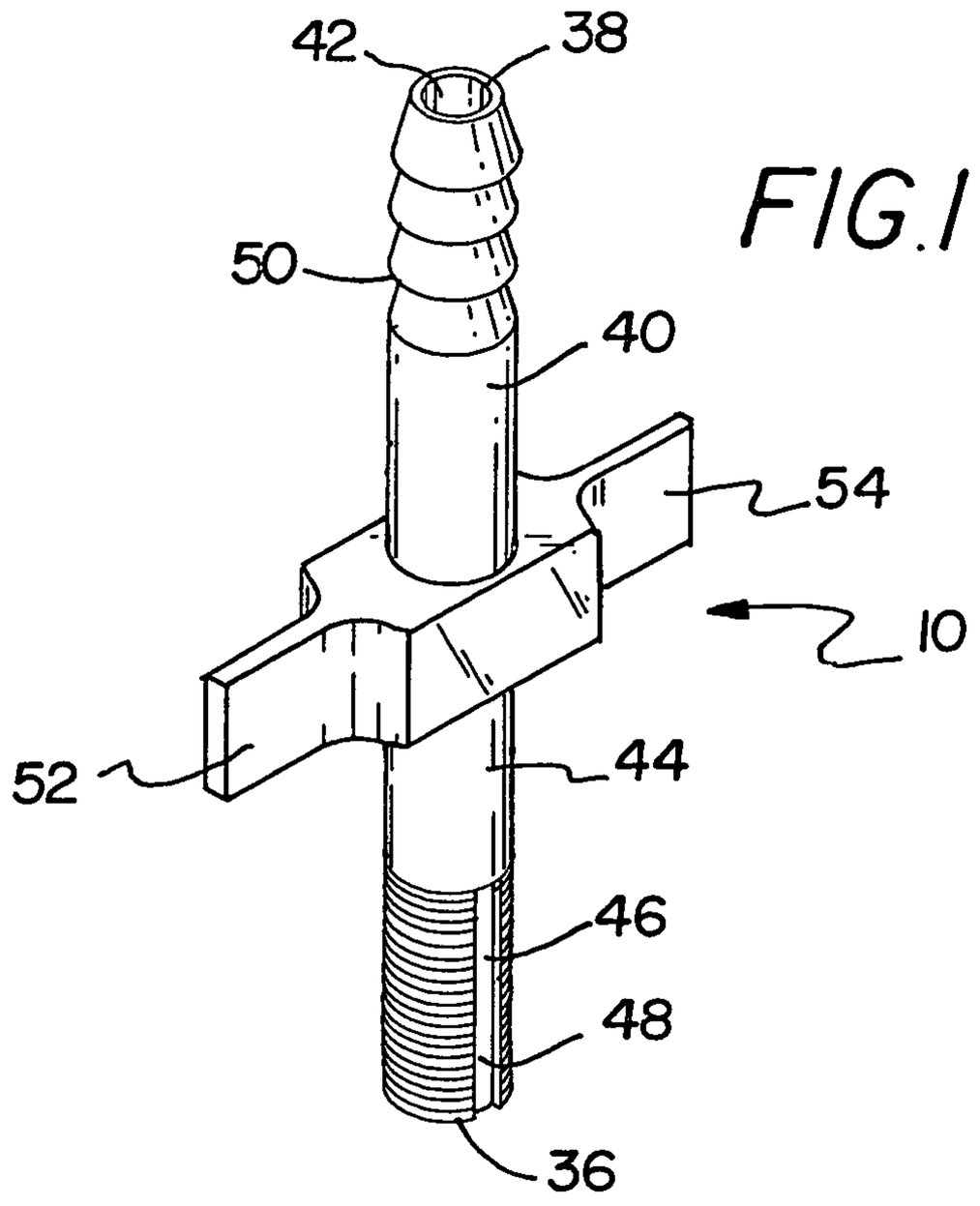


FIG. 1

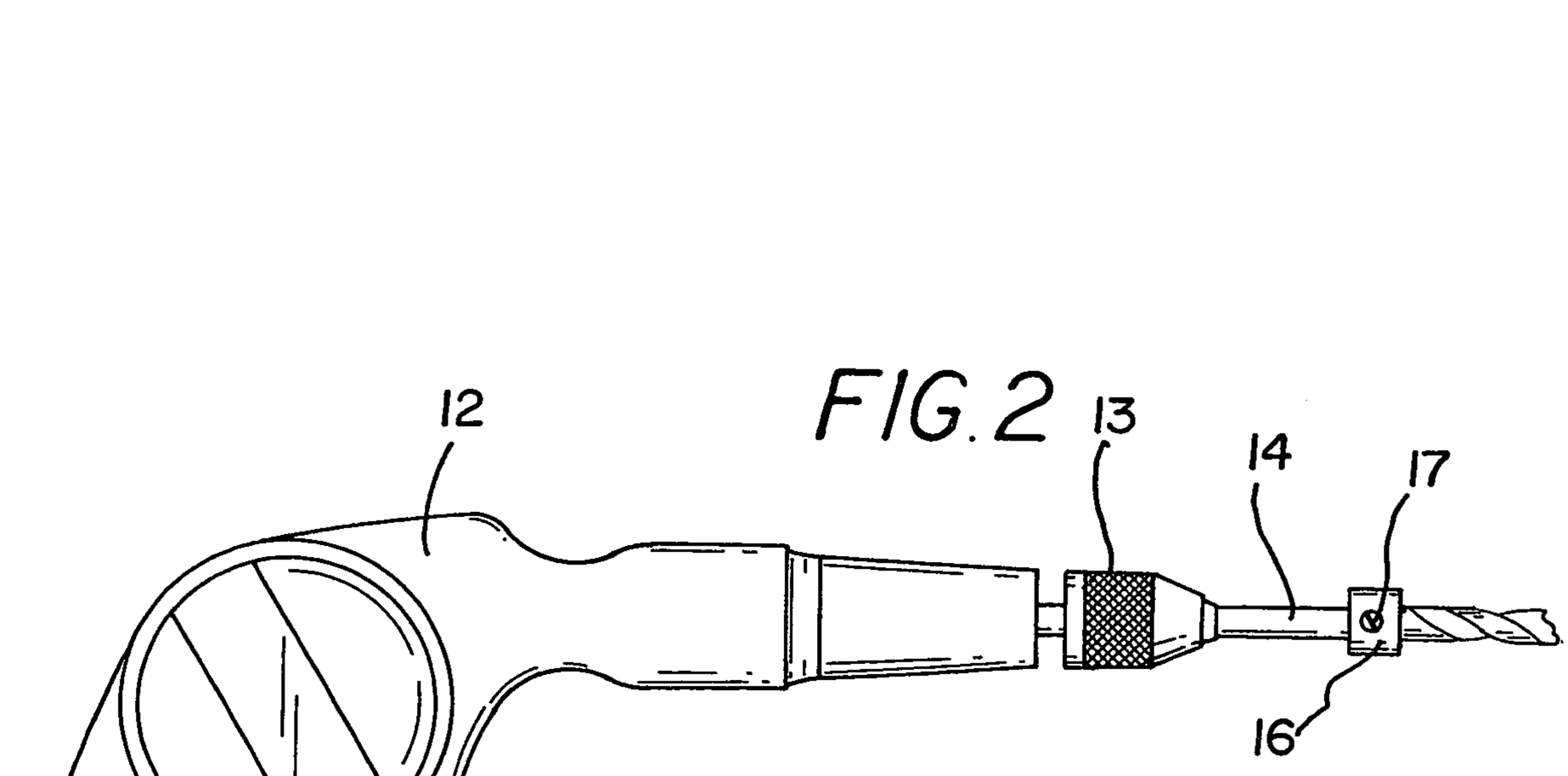


FIG. 2

FIG.3

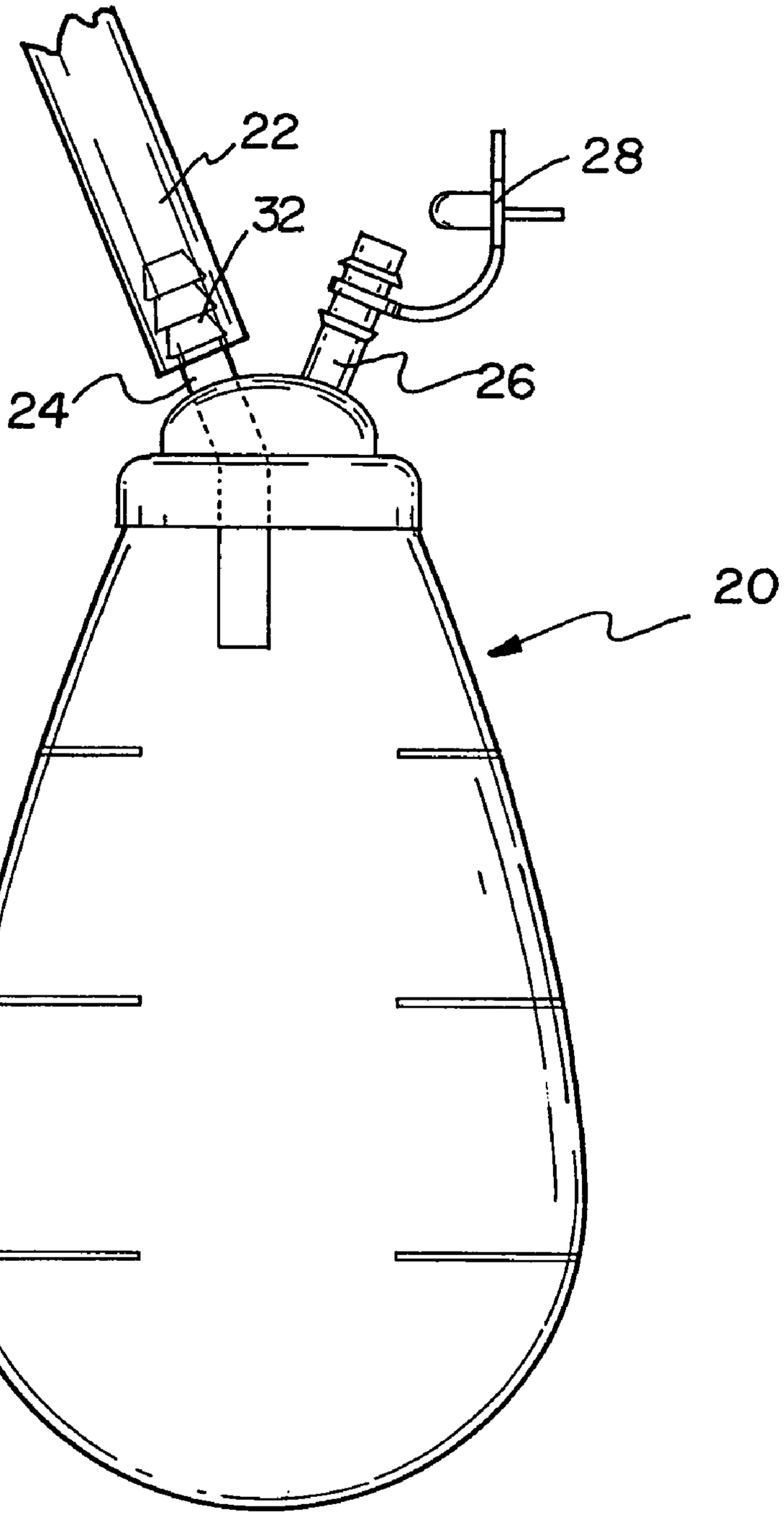
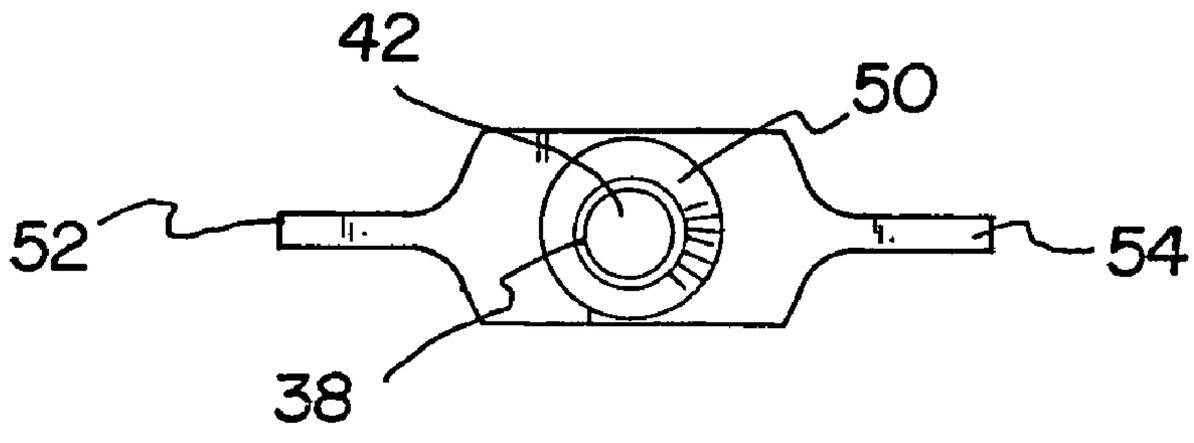


FIG.4



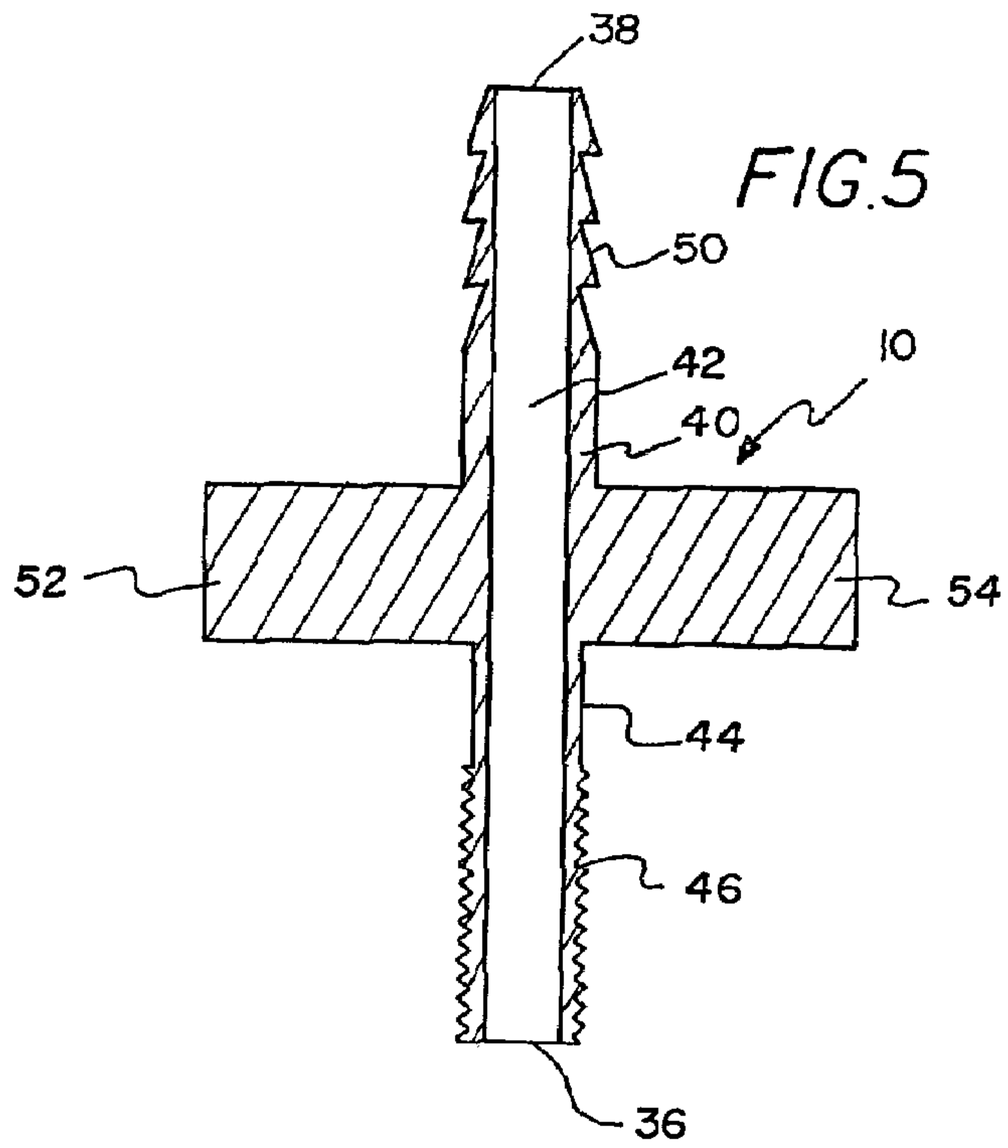


FIG.5

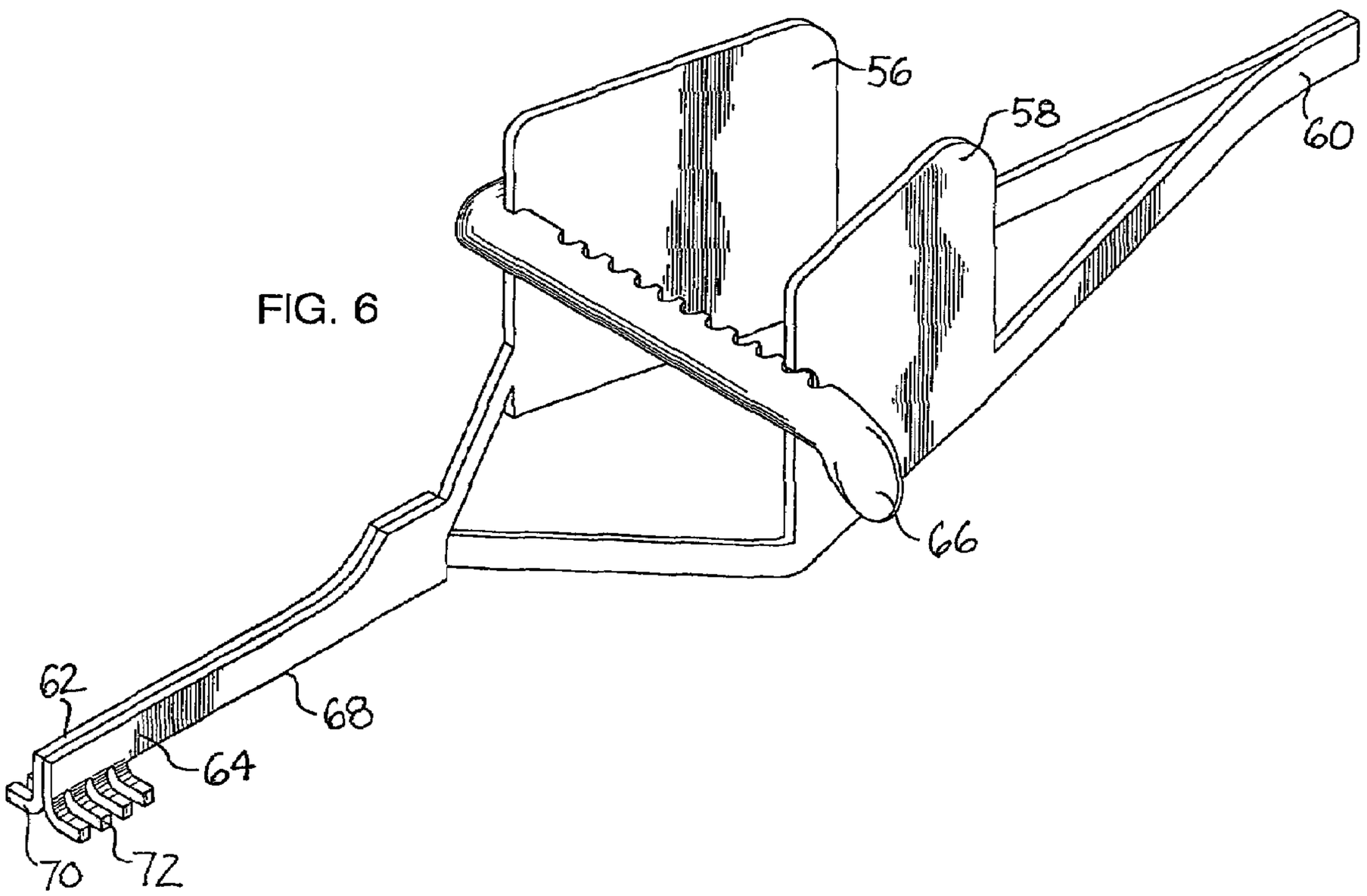


FIG. 6

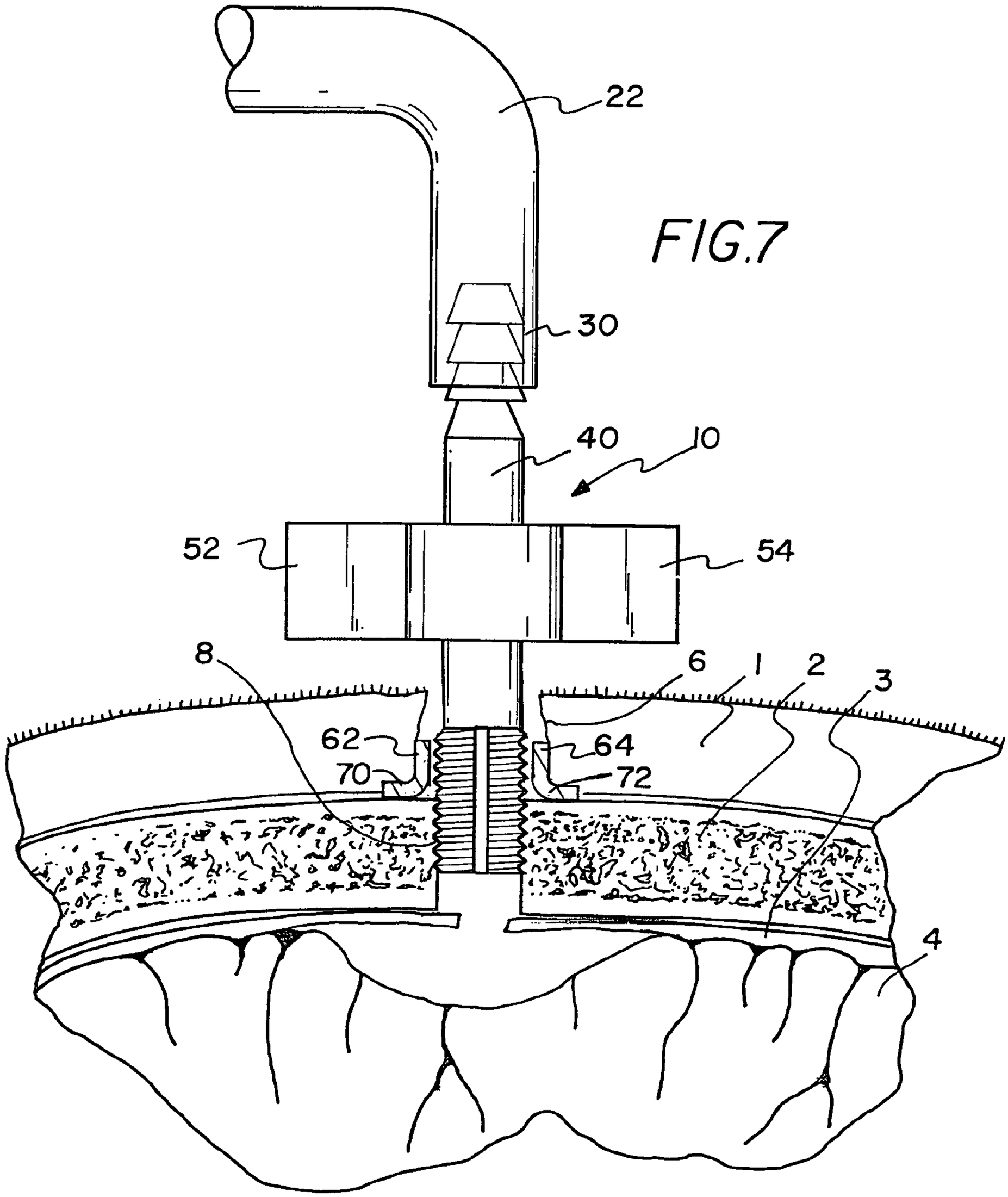


FIG.7

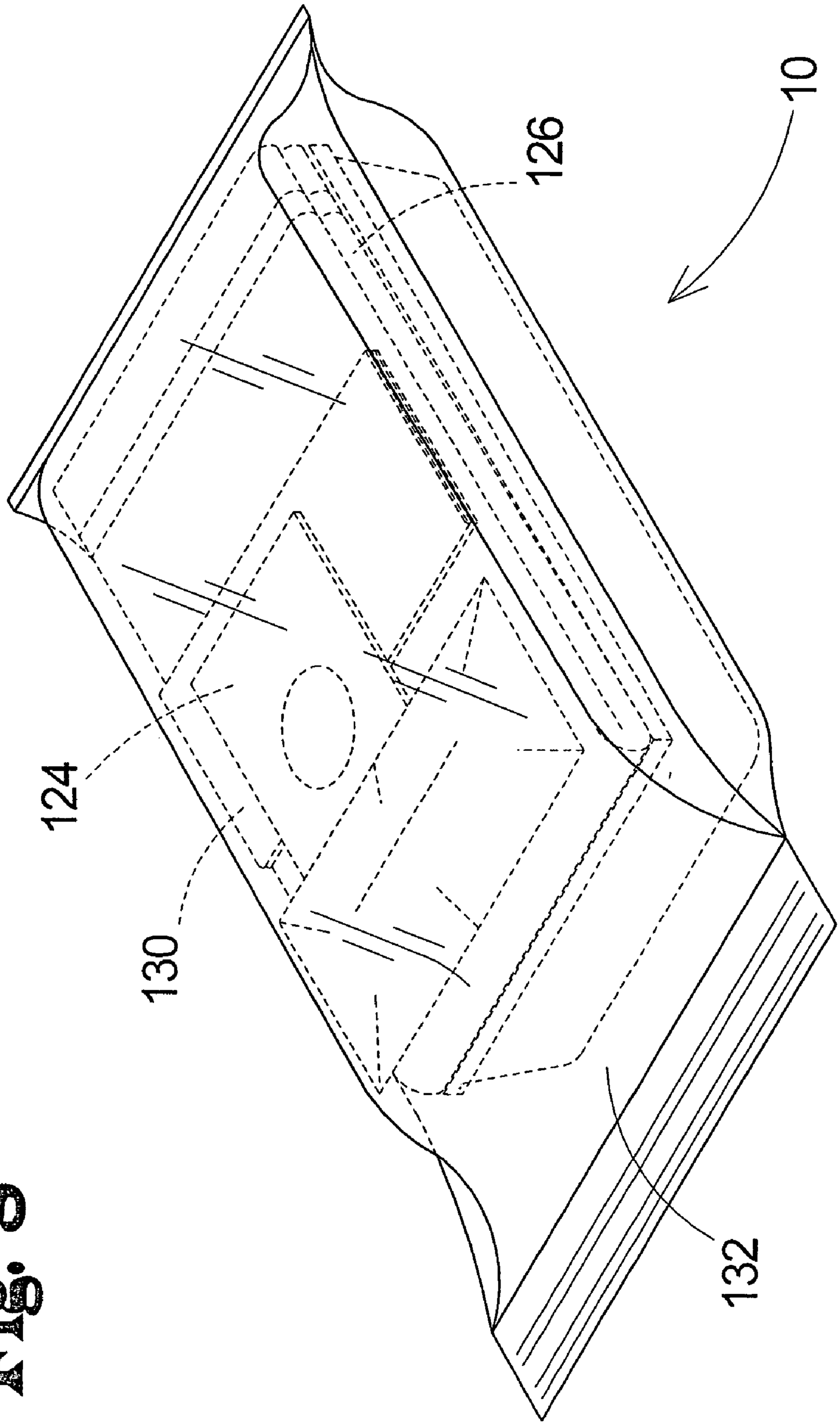


Fig. 8

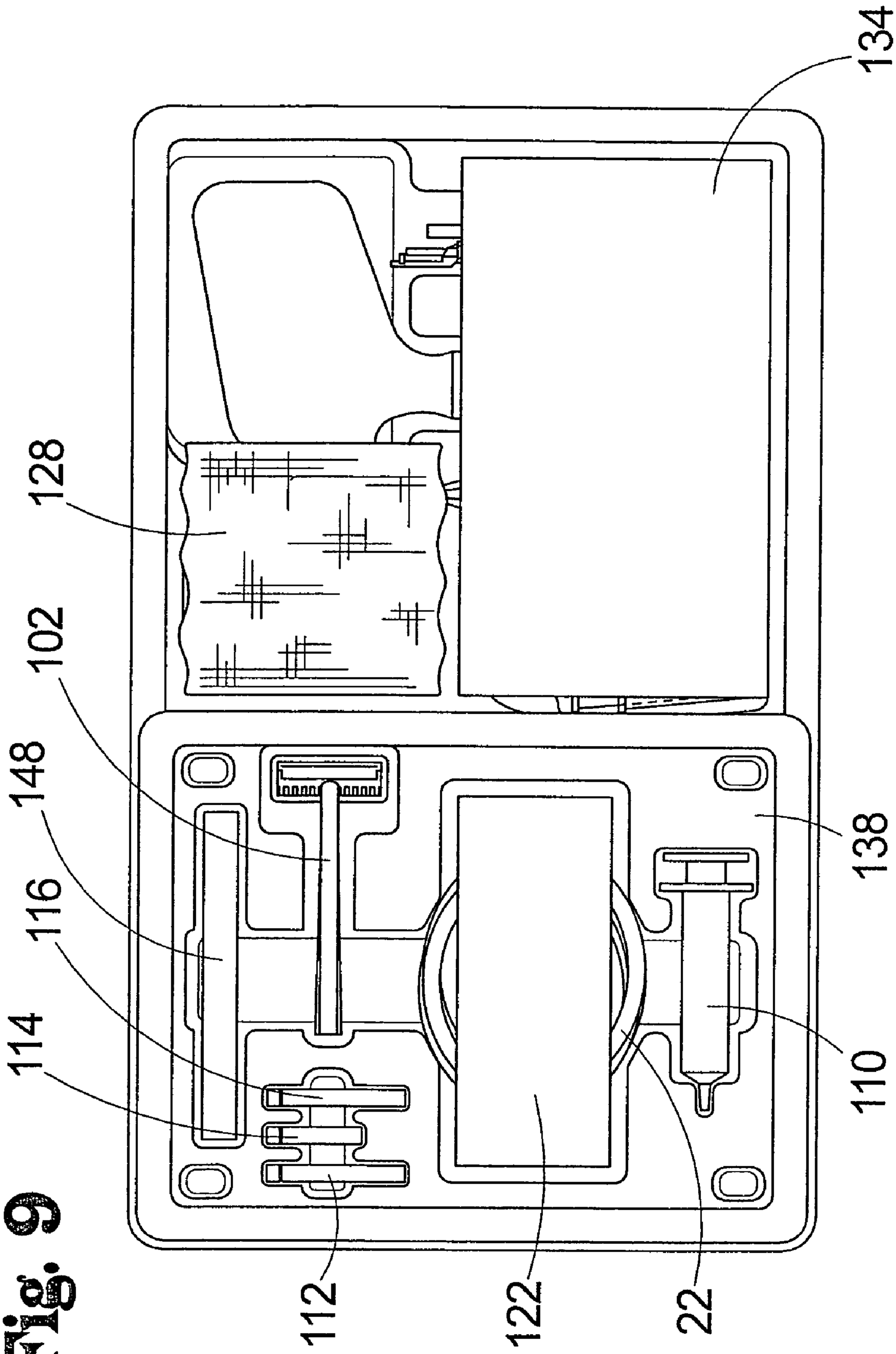


Fig. 9

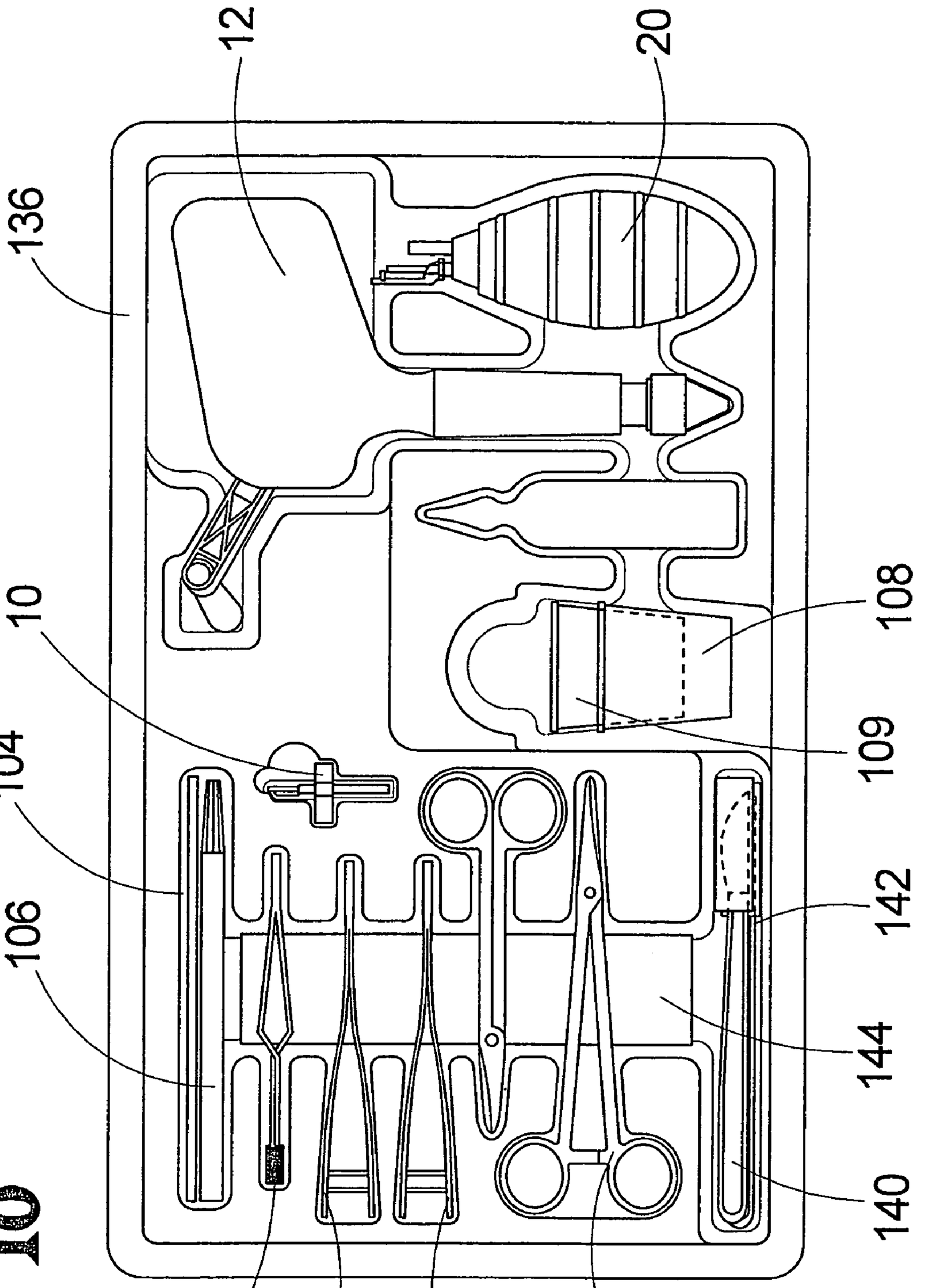


Fig. 10

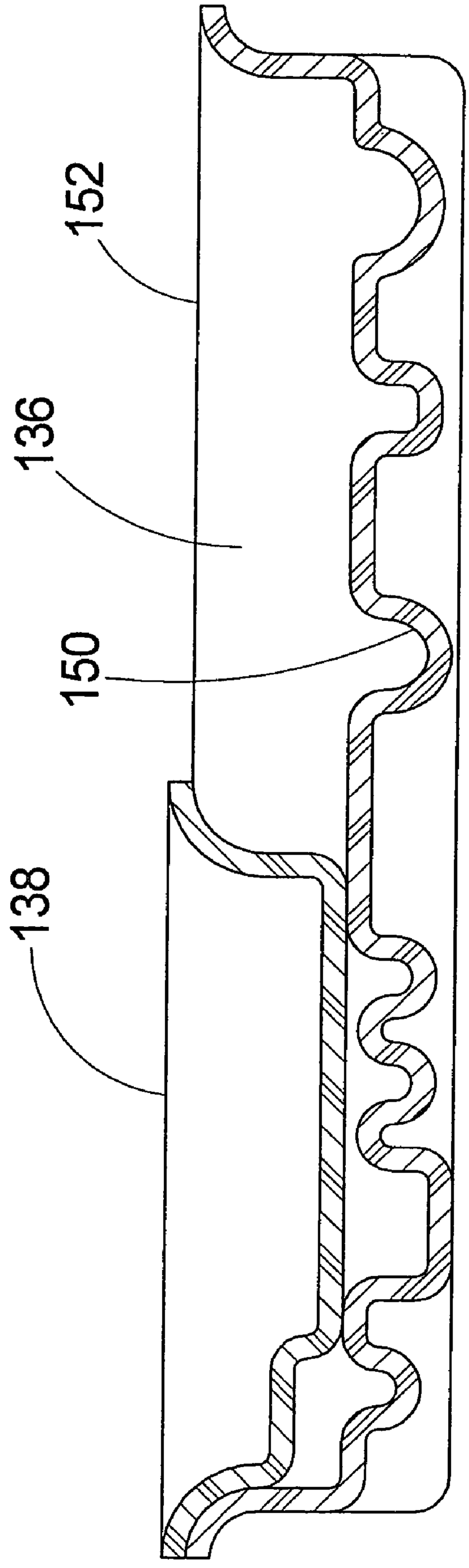


Fig. 11

SUBDURAL EVACUATING PORT SYSTEM

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 09/633,573, filed Aug. 4, 2000 now abandoned, which is a continuation-in-part of application Ser. No. 29/105,951, filed Jun. 4, 1999 now U.S. Pat. No. D,435,291.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to systems for removing fluids from the subdural region of a patient and more particularly pertains to a new subdural evacuating port system for removing subdural fluid accumulations in a manner that is minimally invasive and promotes decompression, expansion, and recovery of the brain.

2. Description of the Prior Art

The subdural space of the human head is the space located between the brain and the lining of the brain, which is referred to as the dura mater (hereinafter referred to as the "dura"). Hemorrhages on the surface of the brain, for example, may cause a condition known as a subdural hematoma. The subdural hemorrhages may have a number of causes. For example, elderly persons may be more susceptible to subdural hemorrhages because as the brain ages it tends to become atrophic and the subdural space between the brain and the dura gradually enlarges. Bridging veins between brain and dura frequently stretch and rupture as a consequence of relatively minor head injuries, thus giving rise to a collection of blood in the subdural space. Further, severe linear acceleration or deceleration of the brain can result in the brain moving excessively with respect to the dura, often causing rupture of the bridging veins or the blood vessels on the surface of the brain, which can in turn cause subdural hemorrhages in the "normal", young, and otherwise healthy brain.

These subdural blood collections can be classified as acute subdural hematomas, subacute subdural hematomas, and chronic subdural hematomas. Acute subdural hematomas, which are associated with major cerebral trauma, generally consist primarily of fresh blood. Subacute subdural hematomas are generally associated with less severe injuries than those underlying the acute subdural hematomas. Chronic subdural hematomas are generally associated with even less severe, or relatively minor, injuries. The chronic subdural hematomas tend to be less dense liquid consisting of very diluted blood.

Another condition involving a subdural collection of fluid is a hygroma, which is a collection of cerebrospinal fluid (sometimes mixed with blood) beneath the dura, which may be encapsulated.

One form of treatment for acute subdural hematomas is the performance of a craniotomy operation. This operation entails the removal (with eventual replacement) of a large portion of the skull, opening of the dura, and evacuation of the collection of blood. The craniotomy frequently necessitates the placement of a subdural drain, which comprises a tube extending through the hole created by the craniotomy and into the subdural space for removing any residual or new accumulation of blood or fluid. The craniotomy is a highly invasive procedure that generally involves significant risk to the patient and an extended recovery period.

Since the subacute and chronic types of subdural hematomas primarily comprise collections of liquid, the treatment may range from the performance of a craniotomy to the use of a burr hole. The burr hole operation generally comprises boring in the skull a hole that is smaller than the portion of skull removed in a craniotomy. The burr hole generally has a diameter of about 14 to 18 mm. Through the burr hole, extensive saline washing of the subdural space may be carried out. Frequently, a drain needs to be left in place through the burr hole, with the end of the drain being in communication with the surface of the brain in order to allow for postoperative drainage of any further accumulations of fluid. Again, the patient is exposed to a fairly invasive procedure and a relatively long recovery period.

The aforementioned drains are frequently typically used in combination with gravity drainage or the application of negative pressure through the tube of the drain. The typical level of the negative pressure applied by the drains frequently causes further hemorrhage of the brain, especially if the end of the tube should come in contact with the surface of the brain. Further, recurrence of subdural hematomas and hygromas is quite common in chronic cases as the brain generally fails to expand to fill the enlarged subdural space created by the collection of fluid. If the subdural space remains enlarged after removal of the fluid, additional fluid tends to collect in the enlarged subdural space. The aforementioned treatment techniques do not actively contribute to re-expansion of the brain within the dura, and therefore do little to prevent the re-accumulation of fluid in the enlarged subdural space.

The subdural evacuating port system according to the present invention substantially departs from the conventional concepts and designs and methods of the prior art, and in so doing provides an apparatus and method primarily developed for the purpose of removing subdural fluid accumulations in a manner that is minimally invasive and promotes decompression, expansion, and recovery of the brain without entering the subdural space or touching the brain.

SUMMARY OF THE INVENTION

In view of the foregoing disadvantages inherent in the known techniques and systems for removing fluids from the subdural region of a patient now present in the prior art, the present invention provides a new subdural evacuating port system with a device and method of use wherein the same can be utilized for removing subdural fluid accumulations in a manner that is minimally invasive and promotes the decompression, expansion, and recovery of the brain.

The invention includes a procedure for treating substantially liquid subdural fluid collections in a manner that is minimally invasive and does not involve touching the brain. Significantly, the procedure of the invention promotes brain expansion within the dura by creating a homogeneous, negative pressure throughout the subdural space from which the fluid collection is removed.

The invention is especially effective when used on patients having a subdural space filled with fluid that is substantially liquid without significant coagulation of the fluid, including acute patients that are taking anticoagulants to enhance the fluidity of the matter that has accumulated in the subdural space.

The invention contemplates a kit for evacuating a collection of fluid from the subdural space of a patient. The kit may include a subdural evacuating port device having a proximal end and a distal end. The subdural evacuating port device has a tubular portion with a lumen extending between the proximal and distal ends. An exterior surface of the proximal end of the tubular portion has self-tapping threads formed thereon for cutting threads into a skull. Retaining means on the exterior surface of the tubular portion adjacent to the distal end are

provided for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion. A pair of wings extend outwardly from the tubular portion in substantially opposite directions. The kit also includes means for performing placement of the subdural evacuating port device in the patent.

The means for performing placement of the subdural evacuating port device may include means for preparing an operative site on the scalp of the patient. The means for performing placement of the subdural evacuating port device may include means for opening an operative site on the patient. The means for performing placement of the subdural evacuating port device may include means for establishing an operative area on the patient. The kit may also include packaging for removably securing other elements of the kit. The means for performing placement of the subdural evacuating port device may include means for maintaining an operative area on the patient.

There has thus been outlined, rather broadly, the more important features of the invention in order that the detailed description thereof that follows may be better understood, and in order that the present contribution to the art may be better appreciated. There are additional features of the invention that will be described hereinafter and which will form the subject matter of the claims appended hereto.

In this respect, before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

As such, those skilled in the art will appreciate that the conception, upon which this disclosure is based, may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present invention. It is important, therefore, that the claims be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present invention.

For a better understanding of the invention, its operating advantages and the specific objects attained by its uses, reference should be made to the accompanying drawings and descriptive matter in which there are illustrated preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood and objects other than those set forth above will become apparent when consideration is given to the following detailed description thereof. Such description makes reference to the annexed drawings wherein:

FIG. **1** is a schematic perspective view of a new subdural evacuating port device of the system of the present invention.

FIG. **2** is a schematic side view of a drill and bit useful in the techniques of the present invention.

FIG. **3** is a schematic side view of a bulb useful in the techniques of the present invention.

FIG. **4** is a schematic end view of the subdural evacuating port device of the present invention.

FIG. **5** is a schematic sectional view of subdural evacuating port device of the present invention.

FIG. **6** is a schematic side view of a retractor useful in the techniques of the present invention.

FIG. **7** is a schematic sectional view of a portion of a patient's skull and brain area with the subdural evacuating port device mounted on the skull.

FIG. **8** is a schematic top exterior view of the packaging of an enhanced kit of implements useful for practicing the method of the present invention.

FIG. **9** is a schematic top view of a main tray and a secondary tray in a nested condition with various implements of the enhanced kit shown therein.

FIG. **10** is a schematic top view of the main tray of the enhanced kit of the present invention with the secondary tray removed from the main tray to reveal additional implements of the enhanced kit.

FIG. **11** is a schematic cross sectional view of the main tray and the secondary tray in a nested condition.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference now to the drawings, and in particular to FIGS. **1** through **11** thereof, a new subdural evacuating port system embodying the principles and concepts of the present invention will be described.

As best illustrated in FIGS. **1** through **7**, the system of the invention generally includes a subdural evacuating port device **10**, and contemplates a kit for evacuating a collection of fluid from a subdural space of a patient that incorporates the subdural evacuating port device. The system also contemplates a method for utilizing the subdural evacuating port device and elements of the kit for removing fluid from the subdural space while facilitating the recovery of the patient's brain.

Elements useful in practicing the invention include the subdural evacuating port device **10**, a drill device **12**, a drill bit **14** for mounting on the drill device, a stop collar **16** for mounting on the drill bit, a retractor device **18**, a negative pressure source **20**, and a conduit **22**.

The drill device **12** is provided for rotating the drill bit **14**. The drill bit is mountable on the drill device in a suitable manner, such as by an adjustable chuck assembly **13**. The chuck assembly **13** of the drill device **12** is most preferably rotated by manual means (e.g., turned by the surgeon's hand), but optionally the chuck assembly may be driven by motorized means.

The drill bit **14** is adapted for removably mounting on the drill device **12**, and the drill bit **14** is preferably sized for creating a opening of a suitable size in the skull of the patient, as will be discussed in greater detail below. Illustratively, the drill bit **14** is formed of a stainless steel material.

The stop collar **16** is preferably provided for selectively limiting the maximum penetration of the tip of the drill bit **14** into the skull of the patient. The stop collar **16** is most preferably selectively lockable in a variety of longitudinal positions along the length of the drill bit **14** depending upon the depth of penetration needed to produce an opening through the skull without injuring the brain. The stop collar **16** is provided with a channel for receiving a portion of the drill bit **14**, and the stop collar has a set screw **17** for extending into the channel and abutting against the drill bit **14** for locking the stop collar in a selected longitudinal position. Illustratively, one suitable material for the stop is a nylon, such as DELRIN.

The retractor device **18** is provided for holding back the edges of an incision made through the scalp of the patient. The retractor device **18** is especially useful for reducing the possibility of contact between the drill bit and the scalp when the

drill bit is inserted through the incision for boring into the skull, and thus reduces any damage resulting from such contact. Preferably, the retraction device is of the type known as an "Holzheimer" retractor (see FIG. **6**). The "Holzheimer" retractor generally has two arms **56**, **58** that are joined together at proximal ends of the arms to form an apex **60**. The arms **56**, **58** extend away from the apex **60** and terminate at free ends **62**, **64** of the arms. Preferably, the free ends of the arms are spaced such that the arms form a substantially V-shaped structure. A locking member **66** may be included on the retractor for selectively locking the arms at a desired spacing. The "Holzheimer" retractor **18** has a lower edge **68** for inserting into the incision. A tab **70**, **72** may be provided on each of the arms **56**, **58** adjacent to the lower edge **68** at a location separated from the apex **60** of the clip. The tabs **70**, **72** preferably lodge themselves below the outer surface of the scalp to help hold the clip in place with respect to the incision during the period when the incision needs to be held open. Optionally, but less preferably, retraction of the scalp may be performed by other known types of surgical retractors, such as, for example, a "Mastoid" retractor, a "Gelpi" retractor, or a "Heiss" retractor.

The negative pressure device **20** is provided for creating a uniform negative pressure condition in the subdural space of the patient. The negative pressure device exerts a suction for imparting a uniform partial vacuum in the subdural space. Importantly, the magnitude of the negative pressure condition created is relatively low for exerting a gentle suction in the subdural space. The substantial uniformity of the negative pressure is considered important for promoting the gradual re-expansion of the brain in the subdural space. The magnitude of the negative pressure exerted by a suitable negative pressure source is approximately 0.8 inch to 1 inch of mercury (Hg) with respect to atmospheric pressure. It will be appreciated that a lower level (e.g., less than 0.8 inches of mercury) of negative pressure may be used, although the effectiveness of the fluid removal will be reduced. While relatively higher levels of negative pressure may be used (such as up to approximately 1.2 inches of mercury), significantly higher levels of negative pressure can hamper the recovery of the brain and the associated tissues, by, for example, causing hemorrhages to occur. The relatively low level of negative pressure permits the negative pressure condition to be maintained in the subdural space for a relatively extended period of time for removing any further collection of fluid, as well as promoting a gradual expansion of the brain in the subdural space during the healing process.

A highly preferable negative pressure source is a device commonly referred to as a Jackson-Pratt bulb (see FIG. **3**). The Jackson-Pratt bulb **20** has an interior and a pair of openings **24**, **26**. More particularly, the bulb **20** has a primary opening **24** and a secondary opening **26**, and each opening extends between the interior and an exterior of the bulb. A check valve (not shown) is provided on the bulb **20** in communication with the primary opening **24** for resisting exit of fluid (e.g., gas or liquid) from the interior to the exterior of the bulb through the primary opening while permitting fluid flow into the interior through the primary opening. A cap **28** may be provided for selectively closing the secondary opening **26** of the bulb thus requiring any fluid entering the interior to enter through the primary opening **24**.

The conduit **22** may be provided for fluidly connecting the subdural evacuating port device **10** with the negative pressure source. Preferably, the conduit **22** connects the primary opening **24** of the Jackson-Pratt bulb **20** with the subdural evacuating port device. The conduit **22** has first **30** and second **32** ends, and the first end **30** is removably connectable to the subdural evacuating port device **10** and the second end **32** is removably connectable to the primary opening **24** of the Jackson-Pratt bulb **20**. The conduit may comprise flexible tubing of the type commonly used for draining fluids from the body, such as, for example, tubing formed from a silicone material. Illustratively, a length of tubing between approximately 2 feet (approximately 60 cm) is suitable.

A highly significant feature of the invention is the subdural evacuating port device **10** for penetrating the skull of the patient. The port device **10** includes a substantially tubular portion **40** with a lumen **42** that extends between a proximal end **36** and a distal end **38** of the port device. An exterior surface **44** of the proximal end **36** of the tubular portion is preferably provided with self-tapping threads **46** formed thereon for cutting threads into the skull of the patient as the proximal end is inserted into an opening **8** in the patient's skull **2** and the port device is rotated in the opening. Illustratively, a longitudinal groove **48** may extend through the self-tapping threads **46** to produce thread cutting surfaces on the exterior surface **44**. An exterior surface **44** of the distal end **38** of the tubular portion **40** preferably has a plurality of annular barbs **50** formed thereon for retaining the conduit **22** on the distal end **38**.

Significantly, the subdural evacuating port device **10** includes a pair of wings **52**, **54** extending outwardly from the tubular portion **40** which facilitate finger rotation of the tubular portion in the opening **8** of the skull **2** during the threading of the opening by the self-tapping threads **46** of the port device. Preferably, the wings **52**, **54** extend in substantially opposite directions for enhancing finger grippability of the wings. The wings **52**, **54** may be mounted on the tubular portion at a location substantially medially between the proximal **36** and distal **38** ends of the tubular portion **40**, between the self-tapping threads **46** and the annular barbs **50**.

In one illustrative and highly preferred embodiment of the port device, the diameter of the exterior surface of the tubular portion measures approximately 6 mm. The lumen has a diameter of approximately 3.8 mm. The length of the tubular portion from the distal end to the proximal portion is approximately 45 mm. The width between the tips of the wings is approximately 23 mm, and the width of the wings is approximately 5 mm. The self-tapping threads extend approximately 10 mm from the proximal end, and the annular barbs extend approximately 15 mm from the distal end.

The method aspect of the invention permits evacuation of a collection of fluid from the subdural space within the skull **2** of a patient. One of the initial acts of the method includes determining the region of the scalp **1** of the patient that is adjacent to the location of the collection of fluid in the subdural space. Preferably, the region is located on the patient's scalp **1** where the collection of fluid has the greatest dimension or measurement in the subdural space of the skull. The location of the greatest dimension of the fluid collection may be determined by performing an imaging study of the head of the patient using, for example, computerized tomography or magnetic resonance imaging to determine the extent of the collection of fluid. Once the greatest dimension of the collection of fluid is determined, the location of the opening to be made through the skull to the subdural cavity is selected on the scalp at a substantially central location corresponding to the greatest dimension of the collection of fluid.

The scalp **1** of the patient may be infiltrated with an anesthetic such as by injecting the anesthetic into the scalp in the region where the subdural collection of fluid has the greatest dimension. Illustratively, the anesthetic may be lidocaine with epinephrine, or other suitable anesthetic.

An incision **6** is created in the scalp **1** to expose the bone of the skull **2** of the patient. The incision **6** extends through the scalp **1**, the subcutaneous tissue, the galea, and the periosteum. The retractor device **18** is introduced into the incision **6** for holding the scalp **1** adjacent to the incision away from the operating area.

An opening **8** is created in the skull **2** of the patient using the drill bit **14** mounted in the drill device **12**. Preferably, the size of the opening **8** formed in the skull may be approximately 3 to 8 mm in diameter. Most preferably, the opening **8** in the skull is approximately 5 to 7 mm in diameter. Ideally, the appropriate size opening is approximately 6 mm in diameter. The size of the drill bit **14** is such that it will create a suitable size opening in the skull.

The dura **3** may then be penetrated by incising the dura of the patient using, for example, a unipolar cautery device. The underlying membranes may be transected with the unipolar cautery device.

Fluid that has collected in the subdural space is removed from the space through the incision in the dura **3**. This removal is most preferably performed through the use of the subdural evacuating port device **10**. The proximal end **36** of the subdural evacuating port device is introduced into the opening **8** in the skull **2**. The port device **10** is rotated in the opening **8** such that the self-tapping threads **46** engage the sides of the opening and pull the proximal end **36** into the opening and secure the port device against unintentional withdrawal of the device from the opening. The dura **3** may be penetrated by the proximal end **36** of the port device **10** for placing the lumen **42** in fluid communication with the subdural area, and any collection of fluid in a subdural space.

A substantially uniform negative pressure condition is created in the subdural space. This negative pressure condition is most preferably created through the lumen **42** of the subdural evacuating port device **10** of the invention. The first end **30** of the conduit **22** is connected to the distal end **38** of the subdural evacuating port device, with the annular barbs **50** retaining the conduit on the port device. The second end **32** of the conduit **22** is connected to the negative pressure source. The primary opening **24** of a Jackson-Pratt bulb **20** is connected to the second end **32** of the conduit **22**. To produce the negative pressure condition in the conduit **22** and the lumen **42** of the port device **10**, the Jackson-Pratt bulb **20** is compressed (such as by hand gripping of the bulb) with the cap **28** removed from the secondary opening **26** to expel as much air from the bulb as possible. The cap **28** is then placed over the secondary opening **26**, and the expansion of the resilient bulb from the collapsed condition produces a negative pressure condition in the interior of the bulb as well as the conduit **22** and the lumen **42** of the port device **10**.

The negative pressure condition created in the lumen **42** of the port device **10** tends to draw fluid collected in the subdural space through the lumen and into the conduit **22** and into the interior of the bulb. The fluid collected in the interior of the bulb may be periodically emptied from the bulb, and the negative pressure condition may be reapplied to the subdural space through the port device using the bulb.

The negative pressure condition may be removed when drainage from the subdural space is no longer observed, or the desired re-expansion of the brain in the subdural space has occurred, or as is determined to be medically advisable. To remove the subdural evacuating port device **10**, the device is rotated (e.g., using the wings **52**, **54**) such that the threads **46** move the port device out of the opening **8**.

In a further embodiment of the invention, such as is shown in FIGS. **8** through **11** of the drawings, additional implements that may be useful in practicing the method of the invention may also be included in an enhanced kit **100** which includes implements in addition to the subdural evacuating port device **10**, and optionally, in addition to the drill device **12**, the drill bit **14**, the stop collar **16**, the retractor device **18**, the negative pressure source **20**, and the conduit **22** described above. The further implements of the kit **100** are intended to provide the physician with a complete, or substantially complete, set of tools for performing the installation of the subdural evacuating port device **10** on the patient at virtually any location, but particularly in the patient's room in a hospital or other care facility, without having to move the patient to a surgical room merely for the installation process. This capability may permit the subdural evacuating port device **10** to be installed in a quicker, more economical manner than would be possible if the procedure is performed in a more formal surgical room setting.

The enhanced kit **100** may include a number of implements useful for preparing the operative site, including a razor **102** for removing hair from the operative site on the head of the patient. The razor **102** may be of a disposable type. The enhanced kit **100** may also include a ruler **104** for measuring distances from anatomical landmarks on the patient to determine the appropriate operative site, and may also be used to set the appropriate position of the stop collar **16** on the length of the drill bit **14** when the position of the stop collar **16** is adjusted on the drill bit to set the depth of the hole to be drilled in the patient's skull. The preparatory elements of the enhanced kit **100** may also include a marker **106** for marking points on the skin of the patient, such as the site of the incision to be made in the aforedescribed manner.

The enhanced kit **100** may also include implements for performing the installation of the subdural evacuating port device **10**, including one or more forceps. The enhanced kit **100** may also include one, or preferably two, cups **108**, **109** for mixing or dispensing anesthetic and anti-bacterial solutions used during the installation procedure of the subdural evacuating port device **10**. The enhanced kit may include a syringe body **110** and at least one needle, and preferably more than one needle. Illustratively, the enhanced kit **100** may include a first, filtered needle **112** suitable for removing an anesthetic solution from a vial, such as an 18 G×1.5 inch (approximately 3.8 cm) size needle. A second needle **114** may be suitable for injecting the anesthetic solution into the scalp of the patient from the syringe body. In the illustrative embodiment of the invention, the second needle is a 25×1.5 inch needle. Optionally, a third needle **116** may also be provided for injecting the anesthetic solution into the scalp, but is a different size (for example, length) from the second needle **114** to provide the physician with a choice of needle sizes to use for this part of the procedure according to preference. The third needle **116** may comprise a 25×⅝ inch (approximately 1.6 cm) size needle. The one or more forceps mentioned above may suitably include a pair of forceps **118**, **120**, such as Adson forceps. In one illustrative embodiment of the invention, one of the Adson forceps has serrations on the ends of the arms for the installation of sutures. The other Adson forcep may have arms with interlocking teeth, such as, for example, an Adson 1×2 forcep, which may be useful for gripping the dura or skin of the patient during the installation procedure. Illustratively, one arm has one tooth while the other arm has a pair of teeth. For closing the incision, the enhanced kit **100** may also include sutures **122**, such as a length of 3-0 nylon suture. Illustratively, the sutures **122** material may be a black monofilament nylon available under the trade name ETHILON from Ethicon, Route 22 West, Somerville, N.J. 08876.

The enhanced kit **100** may include a number of items that are provided for establishing and maintaining the surgical area during the procedure. One element that may be included is a fenestrated drape **124** that may be employed to surround the surgical area during the procedure, and the drape **124** may include an opening with an adhesive applied about the opening to adhere the drape to the skin of the patient about the operative site. The drape **124** may have a size of approximately 15 inches (approximately 38 cm) by approximately 15 inches. Additionally, the enhanced kit **100** may also include one or more absorbent towels **126**, and in the illustrative embodiment there are four towels (although more or fewer could be employed) of an approximate size of 18 inches (approximately 45 cm) by 26 inches (approximately 66 cm), although other sizes may be used. The enhanced kit **100** may also include a number of gauze sponges **128**, which may number up to ten or more and have a size of approximately 4 inches (approximately 10 cm) by 4 inches.

To form packaging for the enhanced kit **100**, a wrap **130** for wrapping and enclosing the other components of the kit **100**. The wrap **130** may comprise a CSR or auto wrap suitable for use in sterilization of the instruments. In one embodiment of the invention, the wrap **130** may have a size of approximately 36 inches (approximately 90 cm) by 36 inches. The wrap **130** may also be used as an auxiliary drape for the procedure for installing the subdural evacuating port device **10**. The enhanced kit **100** may also include a sterilization pouch **132** for enclosing all of the other components of the enhanced kit **100**, and may be formed of a polyethylene material, such as is available under the trade name TYVEK from DuPont Industries, although other optional materials may be used.

Optionally, a package insert **134** with various instructions and precautions may also be included with the enhanced kit **100**.

The enhanced kit **100** may also include a plurality of trays for holding the various implements of the enhanced kit **100**. In the illustrative embodiment, a main tray **136** and a secondary tray **138** are employed to hold the various components of the enhanced kit in place prior to and during usage of the kit to install the port device **10**. The secondary tray **138** may be nested inside the primary tray **136** during storage and transport of the enhanced kit, and then the secondary tray **138** may be removed from its nested condition in the main tray **136** when the procedure to install the subdural evacuating port device is to be performed. Preferably, at least one of the trays **136**, **138**, and ideally both of the trays, includes a plurality of depressions **150** that are formed in the upper surface of the material forming the tray, and these depressions are each formed with a suitable shape to releasably receive one or more of the implements of the kit, so that the implements are held in a relatively secure manner against movement in the trays until a removing force is applied to the implement to pull the implement outwardly from the depression of the tray. In one embodiment of the main tray **136**, a perimeter lip **152** of the main tray is raised above the implement-receiving depressions in the tray so that additional items, such as towels and other soft items may sit in the area above the implement receiving depressions and a plane defined by the perimeter lip of the main tray.

The enhanced kit **100** may also include implements for conducting the procedure of installing the subdural evacuating ports device **10**, including one, and optionally two, scalpels **140**, **142** for cutting the skin of the scalp and also for cutting the dura mater within the skull once it has been exposed. The scalpels **140**, **142** may be a #11 scalpel and a #15 scalpel, which provides the physician with the option of using one or both scalpels according to his or her personal preference.

The enhanced kit **100** may also include a number of implements that are useful for post-port device installation procedures. One of these implements is a dressing **144** for the operative site which is applied over the site after installation of the port device to protect the site. One suitable dressing is sold under the trade name TEGADERM. The enhanced kit **100** may also include a scissors **146**, which is useful for trimming the site dressing **144** and the sutures used in closing the incision.

Optionally, the enhanced kit **100** may also include a needle **148** for penetrating the conduit **22**, preferably at a location close to the installed subdural evacuating port device **10**, to extend into the lumen of the port device **10**. This needle, which may be a spinal needle of a size of 18 G×3.5 inches (approximately 9 cm), may be useful for passing through the lumen of the port device **10** after it has been installed to dislodge and clear blockages from blood clots that may occur adjacent to or in the lumen of the port device **10** that may block drainage or evacuation of the subdural area of the patient.

The enhanced kit **100** may also include various compositions for cleaning the operative site on the patient and for anesthetizing the operative site. These compositions may include a chlorhexidine gluconate (2%) composition, such as is sold under the trade name CHLORAPREP, which may be supplied in an integral applicator from Medi-Flex, Inc. of Leawood, Kansas. Further a providone-iodine ointment may also be included, as well as an Iodophor PVP solution. The enhanced kit **100** may also include a vial of xylocalne with epinephrine.

With respect to the above description then, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

Therefore, the foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

I claim:

1. A kit for evacuating a collection of fluid from the subdural space of a patient, comprising:

a subdural evacuating port device having a proximal end and a distal end, the subdural evacuating port device having a tubular portion with a lumen extending between the proximal and distal ends, an exterior surface of the proximal end of the tubular portion having self-tapping threads formed thereon for cutting threads into a skull, retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion, and a pair of wings extending outwardly in substantially opposite directions from the tubular portion; and

means for performing placement of the subdural evacuating port device in a patient.

2. The kit of claim 1 wherein the means for performing placement of the subdural evacuating port device includes means for preparing an operative site on the scalp of the patient.

3. The kit of claim 2 wherein the means for preparing the operative site on the scalp of the patient includes a razor.

4. The kit of claim 2 wherein the means for preparing the operative site on the scalp of the patient includes a ruler.

5. The kit of claim 2 wherein the means for preparing the operative site on the scalp of the patient includes a marking device.

6. The kit of claim 1 wherein the means for performing placement of the subdural evacuating port device includes means for opening an operative site on the patient.

7. The kit of claim 6 wherein the means for opening the operative site on the patient includes forceps.

8. The kit of claim 6 wherein the means for opening the operative site on the patient includes a syringe body.

9. The kit of claim 6 wherein the means for opening the operative site on the patient includes at least one needle.

10. The kit of claim 6 wherein the means for opening the operative site on the patient includes sutures.

11. The kit of claim 1 wherein the means for performing placement of the subdural evacuating port device includes means for establishing an operative area on the patient.

12. The kit of claim 11 wherein the means for establishing an operative area on the patient includes a fenestrated drape.

13. The kit of claim 11 wherein the means for establishing an operative area on the patient includes absorbent towel.

14. The kit of claim 11 wherein the means for establishing an operative area on the patient includes gauze sponge.

15. The kit of claim 1 additionally comprising packaging for removably securing other elements of the kit.

16. The kit of claim 15 wherein the packaging includes a wrap for wrapping other elements of the kit for sterilization procedures.

17. The kit of claim 15 wherein the packaging includes a sterilization pouch for enclosing other elements of the kit prior to use.

18. The kit of claim 15 wherein the packaging includes at least one tray for holding elements of the kit.

19. The kit of claim 15 wherein the packaging includes a pair of trays, a first one of the trays of the pair of trays being at least partially nestable in a second one of the trays.

20. The kit of claim 18 wherein the at least one tray includes a plurality of depressions formed in an upper surface of the at least one tray, at least one of the depressions being configured to releasably hold an element of the kit.

21. The kit of claim 1 wherein the means for performing placement of the subdural evacuating port device includes means for maintaining an operative area on the patient.

22. The kit of claim 21 wherein the means for maintaining an operative area on the patient includes a dressing.

23. The kit of claim 21 wherein the means for maintaining an operative area on the patient includes a needle for penetrating a conduit when the conduit is connected to the retaining means of the subdural evacuating port device.

24. The kit of claim 1, further comprising:

a flexible conduit extending between first and second ends; and

a suction bulb device having a bulb, a primary opening, and a check valve fluidly connected to the primary opening, wherein the primary opening is configured for releasable, fluid connection with the second end of the conduit.

25. A kit for evacuating a collection of fluid from a subdural space of a patient, comprising:

a subdural evacuating port device having a proximal end and a distal end, the subdural evacuating port device having a tubular portion with a lumen extending between the proximal and distal ends, an exterior surface of the proximal end of the tubular portion having self-taping threads formed thereon for cutting threads into a skull, retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion, and a pair of wings extending outwardly from the tubular portion;

means for performing placement of the subdural evacuating port device in a patient, including:

a suction bulb,

a drill,

a retractor device,

a scalpel,

a syringe body

a needle,

a flexible conduit,

a razor; and

packaging including:

a first tray including a lip and forming a plurality of depressions sized and shaped to receive the suction bulb, the drill, the retractor device, and the scalpel, respectively,

a second tray including a lip and forming a plurality of depressions sized and shaped to receive the syringe body, the needle, the flexible conduit, and the razor, respectively,

wherein the packaging is configured such that upon final assembly, the second tray nests within the first tray with at least a portion of the lip of the second tray abutting at least a portion of the lip of the first tray.

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